K063633

MAR 0 2 2007

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 EST REG No.: 1818910
510(K) CONTACT:	Steve Wentworth Regulatory Affairs Project Manager Tel: (574) 371-4913 Fax: (574) 371-4987
TRADE NAME:	DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves
COMMON NAME:	Tricompartmental Knee Prosthesis
CLASSIFICATION:	Knee joint patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560), Class II Device
DEVICE PRODUCT CODE:	87 JWH
SUBSTANTIALLY EQUIVALENT DEVICES:	Universal Femoral Metaphyseal Sleeve Components: DePuy LPS Knee System (K040281, cleared July 9, 2004) Universal Stem Extensions: S-ROM/Noiles™ PS Total Knee System (K941769, cleared February 1, 1995)

DEVICE DESCRIPTIONS:

DePuy is offering the DePuy Universal Femoral Metaphyseal Sleeve and the DePuy Universal Stem Extenstion components as line extensions to its previously cleared PFC, PFC Sigma, S-ROM, Sigma TC3 Revision Knee and Limb Preservation System (LPS) knee replacement prostheses systems. These additional components are designed to be interchangeable within these four knee systems.

The DePuy Universal Femoral Metaphyseal Sleeve components are a modification to the design of the previously cleared DePuy LPS Metaphyseal Sleeve included in K040281. The Universal Femoral Metaphyseal Sleeve components are available in five sizes. They are also available in nonporous textured finish, fully porous coated and distally porous coated options. The femoral metaphyseal sleeve components are optional components that attach to the femoral knee prostheses components by a taper locking mechanism. Use of adapter components are required for the attachment of the metaphyseal sleeve component to the PFC Sigma, LPS and Sigma TC3 femoral components. The

metaphyseal sleeve attaches directly to the S-ROM femoral component. The threaded distal female portion of the femoral metaphyseal sleeve component receives the male threaded portion of the Universal Stem Extension to provide a stemmed femoral knee prosthesis construct. An optional polyethylene plug component is assembled to the metaphyseal sleeve.

The Universal Stem Extension component is an optional component available in three lengths and eight diameters. The distal portion of the stem extension below the male threaded portion is fluted and terminates in a bullet shaped tip. The stem extension component is perpendicularly quadrifurcated to allow for flexibility of the stem component under physiologic loads. The two smallest component diameters are solid. The DePuy Universal Stem Extension components are a modification to the design of the stem extension components previously cleared in K941769. These components can be attached to the female threaded portion of the Universal Femoral Metaphyseal Sleeve or may be attached without the sleeve to the PFC Sigma and Sigma TC3 femoral components using the adapters. The sleeve component is required for the LPS and S-ROM femoral components. The same male threaded attachment is used to connect the stem extensions to the tibial tray components from the PFC, PFC Sigma and Sigma TC3 Revision knee prosthesis systems. The stem extension in not used for the S-ROM tibial trays.

The Universal Stem and Universal Femoral Metaphyseal Sleeve are both manufactured from Ti6-Al4-V alloy. The porous coating on the Universal Femoral Metaphyseal Sleeve is comprised of sintered microbeads of commercially pure (CP) titanium. The Universal Stem Extension component is substantially equivalent to the S-ROM Knee System slotted stem extension component cleared previously under K941769 and the Universal Femoral Metaphyseal Sleeve component is substantially equivalent to the LPS Metaphyseal Sleeve cleared under K040281.

INDICATIONS FOR USE:

The DePuy Universal Femoral Metaphyseal Sleeve and Universal Stem components are intended for use with the PFC, PFC Sigma, Sigma TC3 Revision Knee, or S-ROM knee prostheses in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. These devices are intended for cemented use only.

The DePuy Universal Femoral Metaphyseal Sleeve and Universal Stem components are also intended for use with the DePuy LPS prosthesis for replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include: Malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement; patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring

extensive resection and replacement; revision for failed previous prosthesis cases requiring extensive resection and replacement; severe trauma requiring extensive resection and replacement. The LPS prosthesis is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The Universal Stem and the Universal Metaphyseal Sleeve components are intended for cemented use only.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The design of the DePuy Universal Femoral Metaphyseal Sleeve is substantially equivalent to the LPS Metaphyseal Sleeve (K040281). Since the intended use and materials used for the subject and predicate device components are the same, the DePuy Universal Femoral Metaphyseal Sleeve is considered to be substantially equivalent to the predicate device.

The design of the DePuy Universal Stem Extension is substantially equivalent to the S-ROM/Noiles Knee slotted stem component. Since the materials and intended use for the subject device components are identical to those for the predicate device, the DePuy Universal Stem Extension is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Mr. Steven J. Wentworth
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P.O. Box 988
Warsaw, Indiana 46581-0988

MAR 0 2 2007

Re: K063633
Trade/Device Name: DePuy Knee Prosthesis System Universal Stem Extensions and Universal Femoral Metaphyseal Sleeves
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: December 5, 2006
Received: December 6, 2006

Dear Mr. Wentworth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

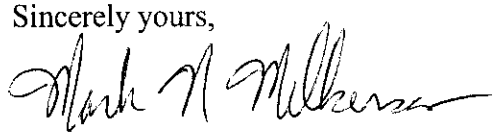
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K063633

Device Name: DePuy Universal Metaphyseal Sleeve and Universal Stem Extension

Intended Use and Indications:

The DePuy Universal Femoral Metaphyseal Sleeve and Universal Stem components are intended for use with the PFC, Sigma PFC, Sigma TC3 Revision Knee, or S-ROM knee prostheses in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention. These devices are intended for cemented use only.

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The Universal Stem and the Universal Metaphyseal Sleeve components are intended for cemented use only.

Mark A Millman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

510(k) Number K063633

Concurrence of CDRH, Office of Device Evaluation (ODE)